

इंटरनेट

मानक

Disclosure to Promote the Right To Information

Whereas the Parliament of India has set out to provide a practical regime of right to information for citizens to secure access to information under the control of public authorities, in order to promote transparency and accountability in the working of every public authority, and whereas the attached publication of the Bureau of Indian Standards is of particular interest to the public, particularly disadvantaged communities and those engaged in the pursuit of education and knowledge, the attached public safety standard is made available to promote the timely dissemination of this information in an accurate manner to the public.

“जानने का अधिकार, जीने का अधिकार”

Mazdoor Kisan Shakti Sangathan

“The Right to Information, The Right to Live”

“पुराने को छोड़ नये के तरफ”

Jawaharlal Nehru

“Step Out From the Old to the New”

IS 6420 (1989): Eye Surgery Instruments - Retractor, Eye Lachrymal Sac, Muller's Pattern (Modified) [MHD 5: Ophthalmic Instruments and Appliances]



“ज्ञान से एक नये भारत का निर्माण”

Satyanarayan Gangaram Pitroda

“Invent a New India Using Knowledge”



“ज्ञान एक ऐसा खजाना है जो कभी चुराया नहीं जा सकता है”

Bhartrhari—Nitiśatakam

“Knowledge is such a treasure which cannot be stolen”

BLANK PAGE



Indian Standard

**EYE SURGERY INSTRUMENTS —
RETRACTOR, EYE LACHRYMAL SAC,
MULLER'S PATTERN (MODIFIED) —
SPECIFICATION**

(First Revision)

भारतीय मानक

नेत्र शल्य क्रिया उपकरण — रेट्रैक्टर, नेत्र अक्षुकोश,
मूलर नमूना (रूपान्तरित) — विशिष्ट
(पहला पुनरीक्षण)

UDC 615.472.5 : 617 764.6

© BIS 1990

BUREAU OF INDIAN STANDARDS
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG
NEW DELHI 110002

June 1990

Price Group 2

FOREWORD

This Indian Standard (First Revision) was adopted by the Bureau of Indian Standards on 20 December 1989, after the draft finalized by the Eye Surgery Instruments Sectional Committee had been approved by the Medical Equipment and Hospital Planning Division Council.

This standard was first published in 1972. The present revision includes certain modifications in order to bring the specification in line with the modern manufacturing practices. Accordingly, the tolerance clause alongwith reference to its relevant standard and requirements have been modified. Clauses on surface finish, passivation and final treatment and sampling plan have been added.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value, observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the round off value should be the same as that of the specified value in this standard.

Indian Standard

EYE SURGERY INSTRUMENTS — RETRACTOR, EYE LACHRYMAL SAC, MULLER'S PATTERN (MODIFIED) — SPECIFICATION (First Revision)

1 SCOPE

1.1 This standard covers the shape, dimensions and other requirements for lachrymal sac retractor used in eye surgery.

2 REFERENCES

2.1 The following Indian Standards are necessary adjunct to this standard:

IS No.	Title
2102 (Part 1) : 1980	General tolerances for linear and angular dimensions (<i>second revision</i>)

IS No.

Title

4905 : 1968

Methods for random sampling

6603 : 1972

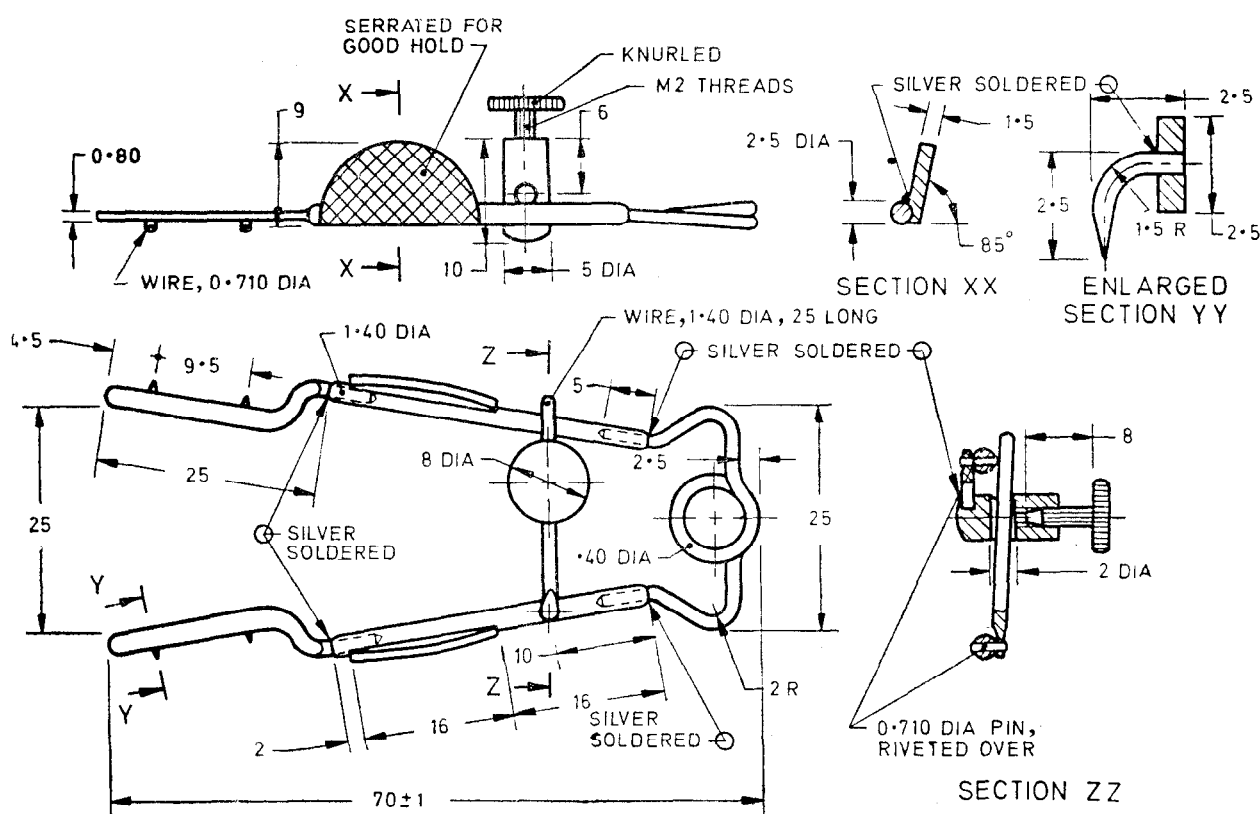
Stainless steel bars and flats

7531 : 1975

Method for boiling and autoclaving test for corrosion resistance of stainless steel surgical instruments

3 SHAPE AND DIMENSIONS

3.1 The shape and dimensions of retractor shall be as given in Fig. 1.



All dimensions in millimetres.

FIG. 1 RETRACTOR, EYE, LACHRYMAL SAC, MULLER'S PATTERN (MODIFIED)

3.2 The tolerance on dimensions of working ends shall conform to 'fine'. Class of deviation and the tolerance for remaining dimensions shall conform to 'medium' Class of deviation of IS 2102 (Part 1) : 1980.

4 MATERIAL

4.1 The retractor shall be made of stainless steel conforming to designation 30Cr13 of IS 6603 : 1972.

5 REQUIREMENTS

5.1 The surface of the working ends shall be free from all defects like burrs, pits and cracks, features, nicks and waviness when examined under $25 \times$ magnification. All surface shall be free from burrs, crevices and grinding marks.

5.1.1 The retractor shall be supplied free from residual scales, acid, grease and grinding and polishing material. Compliance with these requirements shall be checked under $2 \times$ magnification.

5.2 The edges shall be even and rounded. The retracting hooks shall have their tips semi-sharp. The silver soldering shall be neat and sound. The component parts of the locking device shall swivel freely at the junctions with the arms of the retractor. The knurled screw of the locking device shall firmly lock the retractor, when fully tightened. There shall be no lateral movement of the arms in the locked position.

6 HARDNESS

6.1 The retractor shall have a hardness of 400 to 450 HV.

7 PASSIVATION AND FINAL TREATMENT

7.1 The retractor shall be treated by a suitable passivation process.

NOTE — Examples of methods of passivation are by electropolishing or by treating with 10 percent (v/v) nitric acid solution for not less than 30 min at a temperature of not less than 10°C and not exceeding 60°C . The retractor shall then be rinsed in water and dried in hot air.

8 SURFACE FINISH

8.1 The surface shall be one of, or a combination of, the following:

- mirror polished;
- reflection-reducing, for example satin finish, matt black finishes;
- an applied surface coating, for example, for insulation purposes.

NOTES

1 The satin finish shall be effected by an appropriate procedure such as grinding, brushing, electropolishing and, in addition, satin finishing (glass bending or satin brushing). The finish shall be uniform and smooth and it shall reduce glars.

2 Retractor mirror finish shall be adequately ground to remove all surface imperfections and polished to remove grinding marks, resulting in a mirror finish. The mirror finish shall be effected by an appropriate procedure, such as polishing, brushing electropolishing, and mirror buffing.

9 TESTS

9.1 The arms of the retractor in unlocked position, shall be quickly and fully closed and opened 15 times. The locking mechanism shall not interfere in the movements and the arms shall not assume a new set.

9.2 After securely locking the retractor in any position, attempt shall be made by applying a force of 10 N (1 kgf approximately) to open the retractor. The locking arrangement shall not slip and the retractor arms shall not be damaged. The procedure shall be carried out by locking the retractor arms in three different positions.

9.3 Load required to fully close the arms of the retractors, applied at the middle point of the grip, shall be $75 \pm 1.0 \text{ N}$ ($750 \pm 100 \text{ gf}$).

9.4 Corrosion Resistance Test

9.4.1 The retractor shall satisfy the boiling and autoclaving test as specified in IS 7531 : 1975. The retractor shall not show any sign of corrosion after the test. The retractor shall continue work in normal manner after the test.

10 SAMPLING AND CRITERIA FOR CONFORMITY

10.1 The scale of sampling and criteria for conformity of the retractor to the requirement of this specification shall be as agreed to between the purchaser and the supplier. A recommended sampling plan is given in Annex A.

11 MARKING

11.1 Each retractor shall be legibly marked with the identification of the source of manufacture and symbol 'SS' for stainless steel in such a way that it does not impair its functioning.

12 PACKING

12.1 The retractor shall be individually wrapped in moisture-proof paper or packed in polyethylene bags. The hooks shall be suitably protected by wrapping in cotton wool. The contact of retractor and hook shall be avoided, for any damage in transit.

ANNEX A

(Clause 10.1)

SAMPLING AND CRITERIA FOR CONFORMITY

A-1 LOT

A-1.1 In any consignment, all the instruments produced from the same material under similar conditions shall constitute a lot.

A-2 The number of instruments to be selected from each lot shall depend upon the size of the lot and shall be in accordance with col 1 and 2 of Table 1.

Table 1 Scale of Sampling
(Clauses A-2 and A-3.1)

Lot Size (1)	Sample Size (2)
Up to 15	2
16 „ 50	3
51 „ 150	5
151 and above	8

A-2.1 These retractors shall be selected from the lot at random and in order to ensure the randomness of selection, procedure given in IS 4905 : 1968, may be followed.

A-3 NUMBER OF TESTS AND CRITERIA FOR CONFORMITY

A-3.1 All the retractors selected at random in accordance with col 1 and 2 of Table 1 shall be tested for shape and dimensions, material requirements, hardness, surface finish, tests and corrosion resistance. The instrument shall be considered as defective, if it fails to meet any one of these requirements. A lot shall be considered as conforming to these requirements if none of the instruments in the sample is found to be defective in any of these tests.

Standard Mark

The use of the Standard Mark is governed by the provisions of the *Bureau of Indian Standards Act, 1986* and the Rules and Regulations made thereunder. The Standard Mark on products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of that standard under a well defined system of inspection, testing and quality control which is devised and supervised by BIS and operated by the producer. Standard marked products are also continuously checked by BIS for conformity to that standard as a further safeguard. Details of conditions under which a licence for the use of the Standard Mark may be granted to manufacturers or producers may be obtained from the Bureau of Indian Standards.

Bureau of Indian Standards

BIS is a statutory institution established under the *Bureau of Indian Standards Act, 1986* to promote harmonious development of the activities of standardization, marking and quality certification of goods and attending to connected matters in the country.

Copyright

BIS has the copyright of all its publications. No part of these publications may be reproduced in any form without the prior permission in writing of BIS. This does not preclude the free use, in the course of implementing the standard, of necessary details, such as symbols and sizes, type or grade designations. Enquiries relating to copyright be addressed to the Director (Publications), BIS.

Revision of Indian Standards

Indian Standards are reviewed periodically and revised, when necessary and amendments, if any, are issued from time to time. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition. Comments on this Indian Standard may be sent to BIS giving the following reference :

Doc : No. MHD 5 (2142)

Amendments Issued Since Publication

Amend No.	Date of Issue	Text Affected

BUREAU OF INDIAN STANDARDS

Headquarters:

Manak Bhavan, 9 Bahadur Shah Zafar Marg, New Delhi 110002
Telephones : 331 01 31, 331 13 75

Telegrams : Manaksanstha
(Common to all Offices)

Regional Offices:

Telephone

Central : Manak Bhavan, 9 Bahadur Shah Zafar Marg NEW DELHI 110002	{ 331 01 31 331 13 75
Eastern : 1/14 C. I. T. Scheme VII M, V. I. P. Road, Maniktola CALCUTTA 700054	37 86 62
Northern : SCO 445-446, Sector 35-C, CHANDIGARH 160036	2 18 43
Southern : C. I. T. Campus, IV Cross Road, MADRAS 600113	41 29 16
Western : Manakalaya, E9 MIDC, Marol, Andheri (East) BOMBAY 400093	6 32 92 95

Branches : AHMADABAD. BANGALORE. BHOPAL. BHUBANESHWAR.
COIMBATORE. FARIDABAD. GHAZIABAD. GUWAHATI.
HYDERABAD. JAIPUR. KANPUR. PATNA. TRIVANDRUM.